

K103606

**Siemens Medical Solutions USA, Inc.
Oncology Care Systems**

APR 15 2011

Section 5

510(k) Summary

Date Prepared:

November 27, 2010

Submitter: Siemens Medical Solutions USA, Inc.
Oncology Care Systems
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Proprietary Name: ARTISTE™ Solution with SYS_VB50 Update

Common Name: Medical Charged-Particle Radiation Therapy System

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

Product	510(k) Clearance Date	Claim of Equivalence for:
syngo® RT Therapist Connect for RT Therapist version 4.2 including Control Console 12.	K102671 / Oct. 12, 2010	syngo® RT Therapist Connect v4.2 software update SYS_VB50 and Control Console 12, and new licensed features, In-Line kView™ and Multiple X™.
ARTISTE™ Solution (aka ARTISTE MV) RTT v4.1 with MegaVoltage Cone Beam (MVCB) and the OPTIVUE Flat Panel, 160MLC and electron	K072485 / Dec. 27, 2007	ARTISTE™ Solution with the syngo® RT Therapist Connect v4.2 with software update SYS_VB50 and Control Console 12, with the new licensed feature In-Line kView™ using the MVCB with a carbon graphite target, OPTIVUE 1000ART Flat Panel, 160MLC and electron treatment cones and

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Product	510(k) Clearance Date	Claim of Equivalence for:
treatment cones and accessories Including the RT Therapist Assist (off-line) Workspace		accessories. <i>syngo</i> ® RT Oncologist v4.2 including the RT Therapist Assist off-line features.
COHERENCE™ Oncologist v2.0 with Adaptive Targeting and 2D portal image approval.	K060633 / May 01, 2006	<i>syngo</i> ® RT Oncologist v4.2 with Adaptive Targeting and 3D portal image approval.
<i>syngo</i> ® Dosimetrist Workspace v2.7 including the Basic, Advance and Model based Segmentation features.	K101119 / June 16, 2010	<i>syngo</i> ® RT Oncologist v4.2 with Basic, Advance and Model based Segmentation features.
PreScision™ Option*	K082775 / Feb. 19, 2009	ARTISTE™ Solution with the <i>syngo</i> ® RT Therapist Connect v4.2 with software update SYS_VB50 and Control Console 12, and new licensed feature called Multiple X™ and multiple high dose rate and UnFlat energy options.

The ARTISTE™ Solution SYS_VB50 Update as described in this premarket notification has the same intended use and fundamental scientific technical characteristics as the predicate devices listed above.

Description Summary - ARTISTE™ Solution with SYS_VB50 Update

Technological Characteristics:

The ARTISTE™ Solution SYS_VB50 Update to the ARTISTE family of medical linear accelerators is intend to update customers with optional new features and accessories for systems with the *syngo*® RT Therapist and RT Therapist Connect Workspaces (versions v4.1 or v4.2) for the ARTISTE systems. This update is intended to be backwards compatible to the currently cleared ONCOR and PRIMUS family of medical linear accelerators and their Control Consoles (v9.0+ and v11.0+), the RT Therapist (v2.1a or v2.2) and Oncologist v2.0 workspaces.

The technological characteristics of the RT Therapist Connect Workspace v4.2 and Control Console 12 remain unchanged from the currently cleared product (K102671).

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The *syngo*® Software Architecture:

The *syngo*® Suite for Oncology Workspace focused software utilizes the proprietary *syngo*® software architecture design provides a method of delivering customized software applications based on the modality as clinically supporting packages. From these applications SIEMENS utilizes, as part of the Oncology clinical focus package, multiple applications for patient set-up and position verification, treatment localization, treatment verification, portal imaging as well as data processing, image reformatting, display and printing. The currently cleared COHERENCE™ and *syngo*® products also include an array of image-oriented software tools, support for DICOM connectivity and the Siemens Remote Service option.

Refer to Section 11- Design Description, for the Product and Sub-System Requirements Specifications regarding these specific requirements.

General Safety and Effectiveness:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Refer to Section 21 for the Risk Management documentation.

Intended Use:

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-ray photon and electron radiation for the therapeutic treatment of cancer.

The linear accelerator systems are high-dose and high-dose rate medical linear accelerators optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT) and precision stereotactic applications. The stereotactic applications may include single-session radiosurgery, fractionated stereotactic radiation therapy, or fractionated stereotactic intensity modulated radiation therapy for lesions, tumors and conditions anywhere in the head and body where radiation therapy is indicated.

The *syngo*® Suite for Oncology Workspaces:

The *syngo*® workspaces includes a number of *syngo*® based software applications whose indication for use include the viewing, processing, filming, and archiving of medical images. The

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workspaces also permit patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.

The *syngo*® RT Therapist Connect Workspace v4.2, contains software applications that permits patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording. The *syngo*® RT Therapist Connect Workspace v4.2, can be interfaced with third party devices conforming to the DICOM Standard.

The *syngo*® RT Oncologist Workspace v4.2 permits localization, contouring, segmentation, image calibration, and review of treatment plan parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.

Substantial Equivalence:

The Substantial Equivalence comparison chart in Section 12 demonstrates the comparison of the technological characteristics of the new features and their currently cleared predicate devices.

The new features for the *syngo*® RTT Connect Workspace v4.2, the rebranding and updating of the *syngo*® RT Oncologist v4.2 and the modifications to the Linear Accelerator portal imaging system, does not change the intended use of the original *syngo*® RT Therapist or Oncologist Workspaces or the Siemens branded Linear Accelerator Systems.

Bench Testing:

Bench testing in the form of Unit, Sub-System Integration (SSIT), and System Integration (SIT) testing was performed to evaluate the performance and functionality of the new feature and software updates. All testable requirements in the Engineering Requirements Specifications (ERS) keys, Sub-System Requirements Specifications (SSRS) keys, and the Risk Management Hazard keys have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process (PDP).

The software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria as stated in the Test Plans.

Non-Clinical Test Results:

Validation of the new features for *syngo*® RT Therapist Connect Workspace, v4.2 and Oncologist v4.2 has been performed at the System test (ST) level on production prototype devices by appropriately trained and knowledgeable test personnel. System level validation and regression testing has been performed successfully, demonstrating that the software meets the acceptance criteria as noted in the system test plans.

Testing to Consensus Standards:

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The Siemens branded Linear Accelerators with the new features have been tested to meet the requirements for conformity (where applicable) to multiple industry standards. Refer to Sections 9 and 17 for this content.

Substantial Equivalence to Predicates:

The verification testing to the new software features and component requirements for

- In-Line kView™ imaging with the carbon graphite target and the OPTIVUE™ 1000ART Flat Panel,
- the additional high dose rate Unflat energies in Multiple X™,
- the syngo® RT Oncologist v4 with Adaptive Targeting, Advanced and Model Based Segmentation and 3D Image and plan review and approval,
- accessories such as Small cones, Rotational applicators,
- and the OPTIGARD™ collision avoidance system,
- along with the validation of the intended use,

including the regression testing to the existing RT Therapist Connect software v4.2 and the Control Console 12 functional requirements, is intended to support the claim of substantial equivalence to the currently cleared:

- syngo® RT Therapist Connect Workspace, v4.2(K102671),
- the ARTISTE (K072485) medical linear accelerator with the RT Therapist and RT Therapist Assist workspaces, electron cone accessories and a collision avoidance system,
- and to the stereotactic option PreScision (K082775) for high dose rate, unflat energies,
- additionally to the Advanced Segmentation and Model based Segmentation features in the Dosimetrist v2.7 (K101119)
- Image and plan review and approval and Adaptive Targeting in the Oncologist v2.0 (K060633)

Summary:

In summary, it is SIEMENS' belief that the ARTISTE with the Sys_VB50 update does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Christine Dunbar
Senior Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
CONCORD CA 94520

APR 15 2011

Re: K103606

Trade/Device Name: ARTISTET™ Solution with SYS_VB50 Update
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 25, 2011
Received: March 28, 2011

Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, reading "Mary S. Pastel". The signature is fluid and cursive, with the first name "Mary" being more prominent than the last name "Pastel".

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Section 4

Indication For Use Statement

510(k) Number (if known): K103606

Device Name: ARTISTE™ Solution with SYS_VB50 Update

Indications for Use:

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-ray photon and electron radiation for the therapeutic treatment of cancer.

The linear accelerator systems are high-dose and high-dose rate medical linear accelerators optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT) and precision stereotactic applications. The stereotactic applications may include single-session radiosurgery, fractionated stereotactic radiation therapy, or fractionated stereotactic intensity modulated radiation therapy for lesions, tumors and conditions anywhere in the head and body where radiation therapy is indicated.

The syngo® Suite for Oncology Workspaces:

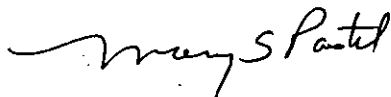
The syngo® workspaces includes a number of syngo® based software applications whose indication for use include the viewing, processing, filming, and archiving of medical images. The workspaces also permit patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.

The syngo® RT Therapist Connect Workspace v4.2, contains software applications that permits patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording. The syngo® RT Therapist Connect Workspace v4.2, can be interfaced with third party devices conforming to the DICOM Standard.

The syngo® RT Oncologist Workspace permits localization, contouring, segmentation, image calibration, and review of treatment plan parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use ☒
(Per 21 CFR 801.109)

510K K103606
OR Over-the-Counter Use ☐

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